REMARKS

Claims 1-25, 39-50, 86-87, and 90-132 are pending in the present application prior to entry of the instant claim amendments. Note, there appears to be an error in the Office Action at page 2, paragraph 2 regarding claims pending in the present application.

Claims 1-25, 39-50, 119 and 120 have been withdrawn from consideration. By virtue of this response claims 91, 93-94, 100, 102, 113-114, and 131 have been cancelled, without prejudice; claims 86, 90, 92, 95-99, 101, 103-105, 110, 118, 124, 127, 129-130, and 132 have been amended, in part for clarity and to correct inadvertent word processing errors. New claims 134-146 have been added. Accordingly, claims 1-25, 39-50, 86-87, 90, 92, 95-99, 101, 103-112, 115-118, 121-130, 132, and 134-146 are currently under consideration.

Support for the amendment to claim 86 can be found at least at page 11, lines 17-25 and page 14, lines 21-23. Support for the amendment to claim 92 can be found at least at the paragraph bridging pages 11-12. Support for new claims 134-135 can be found in the specification at least at page 11, lines 17-25; page 16, lines 16-20; page 30, lines 14-27, and page 39, lines 3-13.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional application.

Applicants request rejoinder of methods claims to the extent they incorporate all the limitations of allowed composition claims. See in re Ochiai.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 86-118 and 121-132 are rejected under 35 USC § 112, first paragraph for allegedly failing to comply with the written description requirement.

Applicants traverse this rejection of claims. The purpose of the written description requirement is to ensure that the specification conveys to those of skill in the art that Applicants possessed the claimed subject matter as of the filing date sought. Applicants submit that one of skill in the art would recognize that Applicants possessed the claimed subject matter as of the filing date of the present application.

The Examiner alleges that the rejection of record as applied to claims 51-85, now cancelled, can be applied to newly added claims 86-118 and 121-132. The Examiner alleges that the claims require the availability of the C antigen to practice the claimed invention. Applicants disagree that the availability of the antigen is required in order to determine whether one antigen binding fragment "competitively inhibits binding to a tumor cell surface epitope" recognized by a second antigen binding fragment. Section 112, first paragraph does not require that Applicants identify the C antigen for the presently claimed invention to be in compliance with Section 112, first paragraph requirements.

Without acquiescing to the Examiner's rejection and solely in the interest of expediting prosecution, claim 86 now recites that the polynucleotide comprises a sequence that encodes an antigen binding polypeptide, wherein the polypeptide comprises the amino acid sequence of the H chain V region or the L chain V region of the polypeptide as shown in SEQ ID NO: 13, wherein the antigen binding polypeptide specifically recognizes a cancer cell surface-antigen and does not recognize a normal non-cancerous cell surface antigen. Applicants submit that one of skill in the art would recognize that Applicants possessed the claimed subject matter as of the filing date of the present application.

Furthermore, Applicants disagree with the Examiner's statement at page 3 of the Office Action that no data beyond the name of the antigen and its presence on cancerous cells has been provided. The present application provides description of the polynucleotide SEQ ID NO: 13 at page 33, lines 21-27; description of the polypeptide SEQ ID NO:14 at the paragraph bridging pages 30-31; and description of methods for assaying binding of an antibody or antigen binding polypeptide to cancer cell surface antigen using specific tumor cell lines. See the specification at

page 64, Example 2 and Example 3. The specification also provides description of H and L chain variable regions of antibody H11. See the specification at page 10, lines 1-28.

Applicants further disagree with the Examiner's statement that there is no reduction to practice of any nucleotide sequence which encodes such antigen binding peptides. See the specification at page 17, lines 1-2 and page 33, lines 21-27, for description of polynucleotide sequences including SEQ ID NO:13.

Applicants submit that the presently claimed invention is in full compliance with Section 112, first paragraph written description requirements.

In view of the above arguments, withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 90-110, 129 and 131 are rejected under 35 USC § 112, first paragraph for allegedly failing to comply with the written description requirement.

Applicants traverse this rejection of claims. Applicants submit that one of skill in the art would recognize that Applicants possessed the claimed subject matter as of the filing date of the present application.

The examiner alleges at page 3 of the Office Action that the written description is not commensurate in scope with the claims which read on polynucleotides that encode consecutive amino acids, consecutive nucleotides, nucleic acid sequences that hybridize under stringent conditions to SEQ ID NO: 13, and substitutions, additions or subtractions of SEQ ID NO: 13. Applicants disagree with this allegation. The specification provides a description of the polynucleotide SEQ ID NO:13, a description of H and L chain V regions, and a description of assays to determine binding characteristics of antigen binding polypeptides encoded by polynucleotides encompassed within the present invention.

Without acquiescing to the Examiner's rejection and solely in the interest of expediting prosecution, the claims have been amended to remove reference to consecutive amino acids and consecutive nucleotides. Claim 92 now recites a polynucleotide that is maintained in a stable

duplex under stringent conditions with a complement of a second polynucleotide, wherein the second polynucleotide encodes an antigen binding polypeptide comprising the amino acid sequences of the H chain V region or the L chain V region of the polypeptide in SEQ ID NO: 13, wherein stringent conditions comprise 0.1X SSC, 75% formamide, and incubation at 68°C, and wherein said polynucleotide encodes an antigen binding polypeptide that specifically recognizes a cancer cell surface protein and does not recognize a normal non-cancerous cell surface protein. The structural and functional components of claim 92 are described in the specification. Applicants submit that claim 129 recites structural and functional components that are described in the specification.

The examiner states at page 4 that with the exception of SEQ ID NO: 13, the skilled artisan cannot envision the detailed structure of the encompassed polynucleotides. Applicants submit that one of skill in the art would be able to envision polynucleotides encompassed by the presently claimed invention and would understand that Applicants were in possession of the claimed invention as of the filing date of the instant application. Applicants submit that the presently claimed invention is in compliance with Section 112, first paragraph requirements.

In view of the arguments above, withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 86-118 and 121-132 are rejected under 35 USC § 112, first paragraph because the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicants traverse this rejection of claims. A specification must adequately teach how to make and use a claimed invention, throughout its scope, without undue experimentation. The instant specification teaches how to make and use the claimed invention. The examiner states at page 6 of the Office Action that the specification is enabling for a ScFv or antibody comprising the

sequence of SEQ ID NO:13. Applicants submit that the specification is enabling for the full scope of the claimed invention.

Without acquiescing to the Examiner's rejection and solely in the interest of expediting prosecution, claim 86 now recites that the polynucleotide comprises a sequence that encodes an antigen binding polypeptide, wherein the polypeptide comprises the amino acid sequence of the H chain V region or the L chain V region of the polypeptide as shown in SEQ ID NO: 13, wherein the antigen binding polypeptide specifically recognizes a cancer cell surface antigen and does not recognize a normal non-cancerous cell surface antigen.

The examiner states at page 6 that the references of record teach that the extent and nature of the antigen which is being targeted must be understood. The examiner states that Westwood et al. teach that a target epitope must be understood for the "best immunogeneic response". Applicants submit that Section 112, first paragraph does not require that any antigen be identified in order for the claimed invention to be enabled. Furthermore, Section 112, first paragraph does not require a disclosure of a "best immunogeneic response" for the claimed invention to be enabled. A specification must adequately teach how to make and use a claimed invention, throughout its scope, without undue experimentation. The specification teaches how to make and use polynucleotides encompassed within the presently claimed invention and further provides assay methods for determining whether additional polynucleotides fall within the claimed invention.

The examiner further states at page 6 that one of the obstacles to successful monoclonal antibody therapy is insufficient target specificity, yet the examiner at page 7 acknowledges that the specification teaches that the H11 antibody is reactive to primary cancerous tissues. Applicants fail to see the relevance of the examiner's statement at page 6, "for an antibody to be somewhat successful, there must be a target", to enablement of the presently claimed invention.

At page 7, the examiner cites references and alleges that there are "shortcomings of potential anti-cancer agents including extrapolating from *in-vitro* to *in-vivo* protocols", problems

with drug testing, and problems with cancer models. The presently claimed invention is directed to polynucleotides encoding antigen binding polypeptides and compositions, vectors and host cells comprising such polynucleotides. Section 112, first paragraph does not require a showing of any *in vivo* results, much less, therapeutic efficacy, for the claimed invention to be in compliance with the requirements. Applicants submit that the specification teaches how to make and use the presently claimed invention without the use of undue experimentation. Applicants submit that the presently claimed invention is in full compliance with Section 112, first paragraph.

In view of the arguments above, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing docket no. **316082000121**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By _____

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